

Group Art Unit 1624
Patent Appl. No. 10/634,827

January 3, 2006
Attorney Docket No. DEAV2000/A043 US NP1

REMARKS

Upon entry of the foregoing amendments, claims 1 to 6, 9, and 10 will be pending in the above-identified patent application. Claims 4, 5 and 6 have been amended. Claim 8 has been canceled by the present amendments. Claim 10 has been added. Support for new claim 10 is found throughout Applicants' specification such as, for example, at pages 62 to 63. No new matter has been added.

In view of the foregoing amendments and the remarks that follow, reconsideration and withdrawal of the rejections are requested respectfully.

Discussion of the Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 4 to 9 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Claim 7 was canceled in the July 18, 2005 Reply, and claim 8 is canceled by the foregoing amendments, thereby rendering the rejection of claims 7 and 8 moot. Applicants amended claims 4, 5, 6, and to replace the phrase "at least one" with the phrase --one or more-- at the Examiner's suggestion. Applicants request respectfully that the rejection of claims 4 to 9 be withdrawn.

Discussion of the Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 5, 6 and 8 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly not being enabling. In particular, it is alleged that the specification does not provide an enabling disclosure for the treatment of "all or any diseases associated with factor VIIa, any or all thromboembolic diseases and any or [all] inflammatory responses" (Action at 3). Applicants traverse this rejection because one skilled in the art having read the present specification and claims would be able to make and use the present inventions without engaging in undue experimentation.

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Claim 5

Claim 5 (and new claim 10) define a method for *inhibiting factor VIIa* utilizing at least one compound of claim 1. The Action alleges that claim 5 is a "reach through claim" through which any or all thromboembolic diseases/disorders are treated (*id.*). Significantly, however, all that is required to practice the invention of claim 5 is to *inhibit factor VIIa* by administration of at least one of the compounds that fall within the scope of formula (I). In view of the guidance provided by Applicants' specification, one skilled in the art would indeed know how to practice the invention of claim 5 without undue experimentation. For example, Applicants' specification, at pages 62 to 63, provides working examples demonstrating the effectiveness of compounds of formula (I) at inhibiting factor VIIa/TF activity. Such inhibitory activity was determined using a technique well known to persons of ordinary skill in the art.¹ Thus, in view of the teachings provided by Applicants' specification, any experimentation that may be required would *not* be undue. *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (Pat. Off. Bd. App. 1986) (experimentation is not undue as long as it is of a routine nature). Accordingly, Applicants respectfully request that the rejection for alleged lack of enablement be reconsidered and withdrawn.

Claim 6

Although Applicants disagree respectfully that a method of inhibiting or reducing inflammatory response is not enabled by the present disclosure, applicants have nonetheless amended claim 6 to delete the phrase "or inflammatory response" for the sole purpose of advancing the prosecution of the present patent application. Accordingly, applicants submit respectfully that this rejection is now moot. Applicants, however, reserve the right to pursue the subject matter deleted from claim 6 in a later-filed continuation application.

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Claim 8

Claim 8 defines a method for treating thromboembolic diseases, comprising administering to a patient in need thereof an effective amount of at least one compound of claim 1. Although Applicants disagree respectfully that the full scope of claim 8 is not enabled by the present disclosure, Applicants have nonetheless canceled claim 8 for the sole purpose of advancing the prosecution of the present patent application. Accordingly, Applicants submit respectfully that this rejection is now moot. Applicants reserve the right to pursue the subject matter of claim 8 in a later-filed continuation application.

Discussion of Replacement of Selected Paragraphs in the Description

A review of Publication No. 2004/0034027 has revealed discrepancies between the Publication and the originally filed application.

The replacement of paragraphs [0007], [0174], and [0217], and replacement of the chemical structure of Example No. 11, does not amend the claims from the previously presented material, but corrects the typographical and omission errors found in Publication No. US 2004/0034027 A1 to conform with the originally presented description.

The last two lines of page 1 of the application as filed on August 6, 2003 contains the phrase "and has the effect of slowing or preventing blood flow in wound healing. Other factors which are not directly related to tissue injury like atherosclerosis and inflammation may". This phrase is omitted in Pub. No. 2004/0034027 A1, paragraph [0007], third to fourth lines of the paragraph.

Page 13, line 2, of the application as filed on August 6, 2003 contains the phrase "1.8 benzyloxy;". In the publication, in paragraph [0174], a hyphen in front of the word "benzyloxy" is found.

¹ The technique is described in J. A. Ostrem et al., Biochemistry 37 (1998) 1053-1059, which is

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Page 17, line 15, of the application as filed on August 6, 2003 contains the phrase "3, 4, 5, 6, 7, 8, 9, or 10 ring atoms". The publication, in paragraph [0217], second line of the paragraph, contains a period in front of the numeral 4.

Page 39, figure 11, of the application as filed on August 6, 2003, shows a chemical drawing of a chiral molecule comprising a wedge indicating a chiral bond between a carbon and a nitrogen. The chemical drawing in the publication, on page 16, does not comprise such a wedge.

None of these typographical and omission errors were found in the parent application 09/965,790, now U.S. Pat. No. 6,645,992.

No amendment to the description is presented by this replacement of this subject matter.

Republication of patent application publication under 37 C.F.R. §1.221 is not requested.

incorporated by reference.

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Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Action of record. Applicants respectfully submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. 18-1982 in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,

Dated: January 6, 2006


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